

("Daily Declaration"), a Petition for an Extension of Time for two (2) months, to and including November 12, 2002 (as November 11, 2002 fell on a Federal Holiday), and a Notice of Appeal, accompanied by the required fee.

IN THE CLAIMS

✓ Please cancel claim 22 without prejudice.

REMARKS

This submission is in response to the Final Office Action dated June 11, 2002. Claims 2, 5-8, 11-14, 16, and 18-24 are pending in this application. Reconsideration of the above identified application, in view of the submitted declaration and the following remarks, is respectfully requested.

Election / Restriction

The Examiner contends that the claims 24 and 18-21 (which are dependent on claim 24) are directed to an invention that is independent or distinct from the invention originally claimed and would require a different search and examination considerations. Applicants respectfully traverse this rejection.

Under 35 U.S.C. § 121, "two or more independent and distinct inventions... in one application may... be restricted to one of the inventions". Inventions are "independent" if there is no distinct relationship between the two or more subjects disclosed" (M.P.E.P. § 802.01). The term "distinct" means that "two or more subjects as disclosed are

related... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (M.P.E.P. § 802.01, July 1988) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (M.P.E.P. § 808.02):

1. Separate classification;
2. Separate status in the art; or,
3. Different field of the search.

Moreover, according to Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (M.P.E.P. § 803) (emphasis added).

Applicants respectfully submit that claim 24 and its dependent claims 18-21 are not distinct or independent such that a new search or different examination consideration would be required. The elements of pending claim 24 can be found in claim 17 of the Response After Final Pursuant of 37 C.F.R. §1.116 filed June 29, 2001. This amendment was entered and considered after a Request for Continued Examination was filed on October 1, 2001. Thus, the examiner has already considered and properly searched the limitations of claim 24.

The specific language objected to in claim 24, *i.e.*, "method for preventing at least one of the symptoms associated with *Streptococcus equi* infection in equine..." is explicitly found in claim 17. Claim 17 was cancelled and replaced by claim 24. *See*, page 4 of the amendment filed March 13, 2001. In addition, similar language can be found in claim

17 as filed in the initial application. Thus the restriction requirement is improper and it is respectfully requested that the Examiner remove the restriction requirement.

In addition, in case the Examiner still finds that the claim had not been previously searched and considered, Applicants respectfully submit that the distinctions designated by the Examiner fail to define inventions that warrant a separate examination and search. Similarly, the distinctions designated by the Examiner fail to distinguish the new method as a separate status in the art. In addition, as provided below, the claims contain a number of unifying features.

A thorough search of the subject matter of claims 2 and 23 would necessarily include a search of the subject matter of claims 24 and 18-21 as they all involve mucosal administration of a live attenuated *Streptococcus equi* in combination with an immunostimulant that stimulates mucosal immunity. Such methods can provide protective immunity against *Streptococcus equi* infection following *Streptococcus equi* challenge. Practicing such methods can also prevent a symptom of *Streptococcus equi* infection, *e.g.*, "strangles." Nasal or mouth administration result in contact with nasopharyngeal mucosa (see claim 23).

In light of the foregoing arguments, it can be concluded that the claims 24 and 18-21 contain multiple unifying features with all of the other claims identified by the Examiner. Hence, it is believed that a single search of the features of the method recited in claims 2 and 23 and the appropriate dependent claims would necessarily and unescapably require a search of the subject matter claims 24 and 18-21. Applicants respectfully submit that the claims designated by the Examiner fail to define a method for using such products that

warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. Thus, the search and examination of every claim is necessarily co-extensive, and in any event would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. Accordingly, applicants respectfully request that the Examiner withdraw the Requirement for Restriction and examine all of the claims in a single application.

Claim Objections

The Examiner has stated that should claim 2 be found allowable, claim 22 will be objectionable under 37 CFR §1.75 as being a substantial duplicate thereof.

In response, Applicant has canceled claim 22 without prejudice, thus obviating this objection.

35 U.S.C. § 103

The Examiner has rejected claims 2, 5-8, 11-14, 16, 22, and 23 as allegedly being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,183,659 ("Timoney et al.") in view of EP0786518 A1 ("Hartford et al."), and U.S. Patent No. 5,597,807 ("Estrada et al.") as further evidenced by Timoney et al., Recent Advances in Streptococci and Streptococcal Diseases, Reedbooks Ltd., 1985: Proceedings of the IXth Lancefield

International Symposium on Streptococci and Streptococcal Diseases held in September 1984, pp. 294-5 ("Timoney II"). Applicants respectfully disagree with the Examiner's contentions.¹

The Examiner contends that the cumulative reference teachings provide both the suggestion and the expectation of success with respect to the Applicant's claimed invention. More specifically, the Examiner contends that the references suggest the alleged improvement of the immune response and protection achieved via the Timoney vaccine with the combination of saponin. The Examiner also contends the references show use of such composition for the protective effects in horses. As discussed below, the Examiner's rejection fails to establish that the combined materials are effective in horses, since the only objective suggestion for such a combination for horses is found in the application under examination. However, or rather in addition, secondary indicia of unobviousness (unexpected superiority leading to commercial success and satisfaction of a long felt need) establish unobviousness of the invention.

The determination of obviousness is based on a series of factual considerations including (1) the scope and content of the prior art, (2) the difference between the art and the claims at issue, (3) the level of ordinary skill in the art, and (4) objective evidence of nonobviousness. *Texas Instruments, Inc. v. U.S. Int'l Trade Commission*, 988 F.2d 1165, 1178, 26 U.S.P.Q.2d 1018 (Fed. Cir. 1993). One such indicia of nonobviousness includes the claimed invention's commercial success. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387 (Fed. Cir. 1988). An examiner cannot disregard this evidence. *Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc.*, 813 F.2d 1207 (Fed. Cir. 1987).

¹ The following arguments apply with equal weight to claims 24 and 18-21.

Furthermore, even if, for the sake of argument, the references cited by the Examiner constitute *prima facie* obviousness, advantages flowing directly from the invention are one consideration that may be relevant to a determination of obviousness. *Mosinee Paper Corp. v. James River Corp. of Virginia*, 22 U.S.P.Q.2d 1657, 1660, *aff'd. mem.* 980 F.2d 743 (Fed. Cir. 1992) (citing *Pre-Emption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 221 U.S.P.Q. 841 (Fed. Cir. 1984). "After all, those advantages are the foundation of that 'commercial success' which may be evidence of nonobviousness." *Pre-Emption, supra*, at 844 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

Applicant respectfully submits a Declaration Under 37 C.F.R. § 1.132 of Robert Daily ("Daily Declaration"), the current Director of the Business Equine Unit for Fort Dodge Animal Health and thus in a position to make such a Declaration, which establishes the commercial interest, commercial success, and long felt need of the claimed invention that result from the superiority of the claimed combination. (Declaration, paras. 1, 2, and 3).

Declarations containing evidence of commercial interest, commercial success, and long felt need must be considered by the Examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. § 103. M.P.E.P. § 716.01(a); *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Stratoflex, Inc. v. Aeroquip Corp.*, (713 F.2d 1530, 1538 (Fed. Cir. 1983).

Mr. Daily states that the live attenuated *Streptococcus equi* and saponin

composition sold under the trademark Pinnacle™ derives its commercial success from its ability to stimulate an effective protective immune response to *Streptococcus equi* in horses by contacting the cells of the nasopharyngeal mucosa, thus preventing strangles in horses. (Daily Declaration, para. 4). The declaration shows a clear nexus between the claimed composition, *i.e.*, a live attenuated *Streptococcus equi* in combination with saponin, and the commercial success. *Id.* Moreover, the composition was marketed to be administered through the nasopharyngeal mucosa. *Id.* Thus, the commercial success is commensurate in scope with the claims.

Gross sales figures provide evidence of commercial success provided there is a showing as to the time period during which the product was sold, *see Ex parte Standish*, 10 U.S. P.Q.2d 1454 (Bd. Pat. App. & Inter. 1988), or a showing of evidence as to market share. *See Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015 (Fed. Cir. 1985).

In February 1998, Applicant's live attenuated *S. equi* and saponin product was commercially introduced into the market as an alternative to a competitor's killed *S. equi* products. (Declaration, para. 5). The declarant indicates gross sales figures in conjunction with time periods during which the Applicant's product was sold and/or indicates market share. Declarant shows that in its first year on the market, Applicant's product had gross sales in the million dollar range. *Id.* After only one year, the claimed invention had a remarkable increase of 44% in gross sales. *Id.* In 2000, the gross sales increased 30% over 1999. *Id.* 2001 showed an increase of gross sales of 13% from 2000 and as of September 2002, sales have already increased 30% over the first nine months of 2001. *Id.* Additionally, the increase

of units sold yearly was dramatic. *Id.* In 1999, there was a 45% increase from the year before while 2000 showed a 30% increase. *Id.* In 2001, there was another 5% increase of units sold and another 2.2% in 2002. *Id.* Note, too, that the value of gross sales increased faster than the number of units sold, which indicates price increases. These sales data thus show increased sales even with rising prices, thus providing ample evidence of commercial success due to product superiority.

Furthermore, the declarant states that the Applicant's claimed invention achieved gross sales greater than the competitors killed product in just its second year as a result of the combination of the live attenuated bacterium combined with saponin, *i.e.*, the claimed subject matter of the patent application. (Declaration, para. 6). The decrease in sales of the competition began at the time the Applicant's invention entered the market and the claimed invention significantly replaced the killed vaccine sold by those competitors. (Declaration, paras. 5 and 6).

Market share provides a strong indication of commercial success. *Ex parte Anderson*, 21 U.S.P.Q.2d 1241 (Bd. Pat. App. & Int. 1991). Applicants claimed invention, from the time of its introduction into the commercial market for sale, demonstrated rapid increases in market share. In addition, the declarant states that while the Applicant's product had significant yearly increases in gross sales, sales of competitor's products, and thereby its market share, dramatically declined. (Declaration, para. 5). Sales of a competitor's killed *S. equi* product, produced by Applicant's direct competitor, Bayer, declined approximately 39% from 1998 to 1999. *Id.* The declarant states that this decrease in sales of the killed vaccine

resulted from the entry of the Applicant's claimed invention into the market in 1998. (Declaration, para. 5). Thus, Applicant's superior product, which is reflected in the claims, replaced competitor's products and exhibited a strong growth in the market share. This establishes commercial success. *See Ex parte Remark*, 15 U.S.P.Q.2d 1498, 1505 (Bd. Pat. App. & Int. (1990)).

Additionally the declarant, currently the Director of the Business Equine Unit for Fort Dodge Animal Health, states that the individuals who are responsible for the health of expensive horses, and who are the users of the claimed invention, would not adopt such a product unless it had substantial efficacy and was safe to use. (Declaration, para. 6). Moreover, the declarant states the increase in sales reflects the superiority of the product and that the product has "reinvented the strangles vaccine market." *Id.* These determinations support the conclusion that the superior quality of the applicant's invention over the competition establishes a clear nexus between the commercial success and the technical advance of the claimed invention. In addition, the rapid and substantial growth in sales and market share, along with the statement that Applicant's product had "reinvented" the market points to a pent-up long felt need for the claimed invention. *See, WMS Gaming Inc. v. International Game Technology*, 184 F. 3d 1339 (Fed. Cir. 1999).

We incorporate all prior responses herein and strongly encourage the Examiner to reconsider the rejections especially in light of this amendment. We reiterate from our last Amendment, which includes the Rule 1.132 declaration of Dr. Li, that Timoney does not teach the use of adjuvants, including those with immunostimulatory properties, or provide any

teaching to suggest such adjuvants. Hartford and Estrada do not remedy this deficiency. Hartford does not motivate, teach, or suggest that any adjuvant stimulates mucosal activity in horses. In addition, Estrada does not use *S. equi* or any comparable antigen, or advocate the use of saponin in horses. Absent some suggestion in the references of the desirability of using saponin in horses, there is no incentive to combine attenuated *Streptococcus equi* (a horse pathogen) with saponin. The Examiner can only support such a conclusion with hindsight gained from the instant application. Hindsight reasoning to combine references can not support an obviousness rejection. *Grain Processing Corp. v. American Maize-Products Corp.*, 840 F.2d 902, 907 (Fed. Cir. 1998).

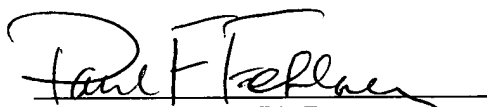
The Daily Declaration submitted herewith provides strong evidence of commercial success and satisfaction of a long felt need for an effective strangles vaccine, and clearly manifests that the invention was not obvious to those skilled in the art at the time the invention was made. When the commercial success of the claimed invention is viewed in light of the Applicant's previous arguments in conjunction with the Declaration of Dr. Li, filed June 29, 2001, it is respectfully submitted that the combination of Timoney et al. in view of Hartford et al. and Estrada et al. as further evidenced by Timoney II does not suggest the making of the claimed invention or does it provide an expectation of success. Therefore, the claimed invention is not obvious to one of skill in the art at the time of the invention.

CONCLUSION

For the reasons stated above, Applicant believes that the pending claims of this

application, as amended, are in condition for allowance. Accordingly, withdrawal of all objections and rejections and reconsideration of the application are respectfully requested. The Examiner is invited to contact Applicant's representative at the below-indicated telephone number if the Examiner believes it would advance prosecution of the application. Allowance of the claims is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul F. Fehlner", written over a horizontal line.

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